

***Meeting Notes: Meeting with David Racine Regarding SPL and Medical Devices
Medical Device Subcommittee, SPL Working Group Process Team, January 10, 2008***

Attendees:

- David Racine, CDRH (FDA)
- Kathy Salazar, Johnson & Johnson Health Care Systems
- Andrea Cleland, Baxter Healthcare Corporation
- Reina Kalish, Baxter Healthcare Corporation
- Charlene Vickers, Ethicon Endo-Surgery
- Denise Oliveira, Genzyme Corporation
- Myron Finseth, Medtronic
- Karin Sailor, Medtronic

The Medical Device Subcommittee met with David Racine of the CDRH Office of Compliance on January 10, 2008 regarding SPL for medical devices and other “e” initiatives within CDRH. The following are notes from the meeting.

To submit questions/comments about the meeting, meeting notes, and/or the Medical Device Subcommittee, please contact Kathy Salazar, Johnson & Johnson Health Care Systems (tel. 732-562-2207; ksalazar@hcsus.jnj.com).

Regarding David Racine’s background and role with SPL

- When asked about his role at FDA and his background with SPL, David indicated that he is with CDRH and that most of his work currently is focused on the Unique Device Identifier (UDI) initiative.
- David indicated that while CDRH is not actively involved in SPL at this point, CDER is highly involved and encouraging other offices with FDA to become more involved.
- With the UDI initiative, SPL could be one potential way to receive UDI info on medical devices. This is one potential pathway for SPL to come into CDRH, but that has not been decided yet.
- CDRH already has other “e” programs, such as the Electronic Registration and Listing System (FURLS) implemented in October 2007. FURLS is a web interface and does not use/require SPL. But David does not rule out that someday SPL could be connected to this in the future.
- All is under discussion. FDA has not announced any plan for implementing SPL for devices.

Regarding questions posed by the group around specific timing and elements of SPL implementation

- David commented that he had no information on the specific details of SPL implementation (e.g., types of devices that will require SPL, availability of guidance documents, required data elements/narrative portion format, etc.) at this time.
- In terms of timing of issuance of FDA guidance around SPL for devices, David indicated that he hoped there would be guidance issued this year for the UDI

requirement, although the law mandating UDI did not specify a required implementation timeline.

- Per David, there are various “e” initiative going on within CDRH currently. He cannot comment specifically because he is not aware of the details, but it is conceivable that SPL could be brought in as part of those initiatives.
- When asked if there was any talk of connecting SPL implementation with the work that is going on for the RPS (Regulated Product Submission) initiative, David indicated he was not aware of any.
- When asked about SPL for eListing as referenced in the PDUFA IV IT plan, David indicated the CDRH “e” strategy is not the same as CDER/CBER's. The PDUFA IV IT plan focuses on CDER/CBER; the CDRH eListing program is separate and already ongoing (implemented in October 2007).

SPL and Harmonization with OUS Standards

- When asked about efforts to harmonize SPL with other OUS standards (Europe [PIM], Sweden, Japan, and Brazil), David indicated that his team was working with GHTF/ GS1 international standards groups as part of the UDI project in recognition of the need for global harmonization.
- If SPL becomes an aspect of UDI as it evolves, then global harmonization would be an aspect for SPL.

Opportunities for Industry Input

- When asked if there are there any FDA opportunities for medical device industry members/representatives to participate in discussions concerning the development of SPL data model, UDI requirements, and the possibility of a UDI database, David indicated that for UDI, the normal process of FDA posting proposed regulations and/or guidance, followed by a comments period, would occur.
- An additional public hearing could occur as well as means of gathering comments from industry and other stakeholders (an initial public hearing already has occurred for UDI). This would be one opportunity to provide input/comments/feedback from industry.
- He encouraged the SPL Medical Device subteam to keep in touch with HL7 and the SPL Working Group; also to check the UDI page regularly on the CDRH website for information as it becomes available.
- CDRH meets informally with groups such as ours to get information; that is another way we could provide industry input.